

REMARKS

Claim Summary

Claims 1-27 are pending. Claims 1-16 and 21-27 are withdrawn.

Claim Rejections under 35 USC 102

Claims 17-20 stand rejected under 35 USC 102(e) as being allegedly anticipated by Solem et al. (US 2003/0135267).

Independent claim 17 recites a method of modifying target tissue shape, including providing a tissue shaping device comprising proximal and distal anchors, a connector disposed between the proximal and distal anchors, and a focal deflector; placing the tissue shaping device in a lumen adjacent the target tissue; applying a shaping force from the focal deflector against a lumen wall to modify the shape of the target tissue; and expanding the proximal and distal anchors to anchor the device in the lumen.

Claim 17 recites a tissue shaping device that comprises both a connector *and* a focal deflector. In addition, as stated in Applicants' application as filed, "The use of a focal deflector tissue reshaper aimed at target tissue adjacent to the lumen minimizes the risk of adverse consequences from altering the shape of non-target tissue adjacent to other parts of the lumen." (Paragraph [0029]). The focal deflector therefore applies a force against the lumen wall and modifies the shape of only the target tissue. As an example, and in reference to the elected species of Figure 9, Applicants' specification states "the focal deflector 88 is straighter than the connector portions extending distally and proximally from it to the distal and proximal anchors." (Paragraph [0045]). *Also see* Applicants' Figure 1.

Solem at most shows two anchors and a connector between the two anchors (*see* Figs 21-25), and therefore does not disclose a tissue shaping device comprising a connector *and* a focal deflector as required by claim 17. Accordingly, Solem can not disclose the method step of applying a shaping force from the focal deflector against a lumen wall to modify the shape of the target tissue. As such, Solem does not disclose each and every limitation of claim 17 and therefore does not anticipate claim 17.

Claim 18 partially recites "applying a proximally directed force on the device; and expanding the proximal anchor while applying the proximally directed force." Exemplary support for these method steps can be found in Applicants' paragraph [0034]. Solem, on the

other hand, expands both stents without applying a proximally directed force on the device as required by claim 18 (*see* Solem paragraph [0146], lines 8-17). Because Solem does not apply a proximally directed force on the device, Solem also does not disclose expanding a proximal anchor while applying a proximally directed force, as further required by claim 18. Solem therefore does not anticipate claim 18 because Solem does not disclose each of the limitations of claim 18.

Dependent claim 19 depends from claim 17 and partially recites that the placing step comprises orienting the focal deflector away from the lumen axis and toward the target tissue. Because Solem does not disclose a device with a focal deflector, Solem can not disclose the method step of orienting the focal deflector away from the lumen axis and toward the target tissue. Solem therefore does not anticipate claim 19.

Dependent claim 20 depends from claim 17 and partially recites that the placing step comprises orienting the focal deflector away from the lumen axis and away from the target tissue. Because Solem does not disclose a device with a focal deflector, Solem can not disclose the method step of orienting the focal deflector away from the lumen axis and away from target tissue. Solem therefore does not anticipate claim 20.

Double Patenting Rejection

Claim 17 stands rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claim 15 of U.S. Patent No. 6,908,478 (“‘478”).

Claim 15 of the ‘478 patent recites numerous limitations that are not present in claim 17 of the instant application. In addition, claim 15 does not recite a focal deflector as claimed in the instant application. Claim 15 merely recites a cable extending proximally from the first anchor and through the second anchor, and makes no mention of a focal deflector as claimed. As such, Applicants respectfully request the double patenting rejection be withdrawn.


CONCLUSION

Applicants request reconsideration and allowance of all claims pending in this application. If a telephone conference would expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Respectfully submitted,

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